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EXAMINER

SHELL, LAURA C

ART UNIT	PAPER NUMBER
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3767

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 09/548,465	Applicant(s) BENCINI ET AL.	
	Examiner LAURA C. SCHELL	Art Unit 3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 October 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 45,47,48,50-54,65,68-71,73-81,83-87,89,90,92-96 and 99-103 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 45,47,48,50-54,65,68-71,73-81,83-87,89,90,92-96 and 99-103 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|-----------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>8/6/2009</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 47, 48, 50, 51, 80 and 81 are rejected under 35 U.S.C. 102(b) as being anticipated by Kovalcheck (US Patent No. 5,472,017). Kovalcheck discloses an apparatus (Figs. 2 and 9-12) comprising: an elongate body defining a diameter, a proximal portion and a distal portion (Fig. 2) and including a wall (Figs. 9-12, the wall is portion 26 as seen in Fig. 12, please note that the reference refers to 26 as a tubular member, and that the inner and outer surfaces are formed by 132 and 44. The examiner believes this is a reasonable interpretation of a wall, as walls within houses are formed with two pieces of drywall and framing between them, and Applicant has not claimed that the wall must be a solid wall with only two surfaces) defining an inner surface (inner surface is 44 in Fig. 12), an outer surface (labeled as 132 in Fig. 11) and a lumen extending from the proximal portion to an aperture in the distal portion (Fig. 12 discloses the lumen extending through to the aperture in the distal end); a stiffening member (Fig. 11, 137) associated with the distal portion of the elongate body and defining a proximal end (near 133), a distal end (near 134a), a length that extends from the proximal end to the distal end, a proximal half that occupies one-half of the length

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and a distal half that occupies one-half of the length (Fig. 11 for example); an anti-tear device positioned within the elongate body wall between the inner surface and the outer surface adjacent to at least a portion of the proximal half of the stiffening member and not adjacent to the distal half of the stiffening member (anti-tear device is being interpreted as 133), and configured to prevent the stiffening member from tearing through the elongate body when the stiffening member bends (the shape of 133 allows it to perform the same function as Applicant's anti-tear device and prevents the stiffening member from tearing the device when it bends); and a steering wire (110a) which is not connected to the anti-tear device and which is not located within the stiffening member (110a is connected only to portion 134a as seen in Fig. 12), having a distal portion operably connected to the distal portion of the elongate body (Fig. 12 discloses that 110a is connected to the distal portion of the elongate body at 134a); wherein the stiffening member and the distal portion of the steering wire are substantially diametrically opposed from one another (col. 11, lines 35-49 disclose that an embodiment in which only one pull/steering wire exists and that the axial spine/stiffening member is placed diametrically opposite the steering wire).

In reference to claim 48, Kovalcheck discloses that the anti-tear device is secured to the stiffening member (Fig. 11).

In reference to claim 50, Kovalcheck discloses that the anti-tear device is a tubular member (Fig. 11 discloses that 133 is tubular).

In reference to claim 51, Kovalcheck discloses that the anti-tear device comprises a tubular member with a slot (Fig. 11).

In reference to claim 80, Kovalcheck discloses that the distal portion of the steering wire is secured to the elongate body at a location within the wall between the inner surface and the outer surface (Fig. 12).

In reference to claim 81, Kovalcheck discloses that the stiffening member is located within the elongate body wall between the inner surface and the outer surface (Figs. 11 and 12).

Claims 65 and 87 are rejected under 35 U.S.C. 102(b) as being anticipated by Kovalcheck (US Patent No. 5,472,017). Kovalcheck discloses an apparatus (Figs. 2 and 9-12) comprising: an elongate body defining a diameter, a proximal portion and a distal portion (Fig. 2) and including a wall (Figs. 9-12, the wall is portion 26 as seen in Fig. 12, please note that the reference refers to 26 as a tubular member, and that the inner and outer surfaces are formed by 132 and 44. The examiner believes this is a reasonable interpretation of a wall, as walls within houses are formed with two pieces of drywall and framing between them, and Applicant has not claimed that the wall must be a solid wall with only two surfaces) defining an inner surface (inner surface is 44 in Fig. 12), an outer surface (labeled as 132 in Fig. 11) and a lumen extending from the proximal portion to an aperture in the distal portion (Fig. 12 discloses the lumen extending through to the aperture in the distal end); a steering wire (110a) having a distal portion that is located within the elongate body wall between the inner surface and

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the outer surface and is operably connected to the distal portion of the elongate body (distal portion of 110a is connected to the distal portion of the elongate body via its connection at 134a); a stiffening member (137) associated with the distal portion of the elongate body and defining a proximal end (near 133); and an anti-tear device (133) defining a proximal end and a distal end, secured directly to the proximal end of the stiffening member (Fig. 11) such that the proximal end of the anti-tear device is located within the distal portion of the elongate body wall between the inner and outer surface (Figs. 11 and 12); wherein the elongate body defines a distal end (near 30) and at least a portion of the stiffening member is located proximal of the distal end of the elongate body (Fig. 11) and wherein the steering wire is not directly connected to the anti-tear device (Figs. 11 and 12 disclose that 110a runs through 24 and is only directly connected to 134a) and is substantially diametrically opposed to the stiffening member (col. 11, lines 35-49 disclose that an embodiment in which only one pull/steering wire exists and that the axial spine/stiffening member is placed diametrically opposite the steering wire).

In reference to claim 87, Kovalcheck discloses that the stiffening member is located within the elongate body wall between the inner surface and the outer surface (Figs. 11 and 12).

Claims 68, 89, 90 are rejected under 35 U.S.C. 102(b) as being anticipated by Kovalcheck (US Patent No. 5,472,017). Kovalcheck discloses an apparatus (Figs. 2 and 9-12) comprising: an elongate body defining a proximal portion and a distal portion (Fig. 2) and a diameter, the distal portion defining a longitudinal axis, and including a wall (Figs. 9-12, the wall is portion 26 as seen in Fig. 12, please note that the reference refers to 26 as a tubular member, and that the inner and outer surfaces are formed by 132 and 44. The examiner believes this is a reasonable interpretation of a wall, as walls within houses are formed with two pieces of drywall and framing between them, and Applicant has not claimed that the wall must be a solid wall with only two surfaces) defining an inner surface (inner surface is 44 in Fig. 12), an outer surface (labeled as 132 in Fig. 11) and a lumen extending from the proximal portion to an aperture in the distal portion (Fig. 12 discloses the lumen extending through to the aperture in the distal end); a stiffening member (137) defining a proximal portion and a distal portion, associated with the distal portion of the elongate body such that the stiffening member will apply force over an elongate body surface area when the stiffening member is bent (Fig. 11); anti-tear means (133) secured directly to the proximal portion of the stiffening member (proximal portion of 137 is secured directly to 133 as disclosed in Fig. 11) and located within the elongate body wall between the inner surface and the outer surface, for increasing the elongate body surface area over which the force is applied when the stiffening member is bent to prevent the stiffening member from tearing through the elongate body (Fig. 11); and a steering wire (110a), which is not connected to the anti-tear means (only connected to 134a), having a distal portion operably connected to the

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distal portion of the elongate body (Fig. 12), wherein the stiffening member and the distal portion of the steering wire are offset from one another by about 180 degrees about the longitudinal axis (col. 11, lines 35-49 disclose that an embodiment in which only one pull/steering wire exists and that the axial spine/stiffening member is placed diametrically opposite the steering wire).

In reference to claim 89, Kovalcheck discloses that at least a portion of the steering wire is located within the elongate body wall between the inner surface and the outer surface (Figs. 11 and 12).

In reference to claim 90, Kovalcheck discloses that the stiffening member is located within the elongate body wall between the inner surface and the outer surface (Figs. 11 and 12).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

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4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 69, 73, 74, 92 and 99 and 102 and 103 rejected under 35 U.S.C. 103(a) as being unpatentable over Kovalcheck (US Patent No. 5,472,017) in view of Savage et al. (US Patent No. 5,507,725). Kovalcheck discloses an apparatus (Figs. 2 and 9-12) substantially as claimed comprising: an elongate body defining a proximal portion and a distal portion (Fig. 2) and including a wall (Figs. 9-12, the wall is portion 26 as seen in Fig. 12, please note that the reference refers to 26 as a tubular member, and that the inner and outer surfaces are formed by 132 and 44. The examiner believes this is a reasonable interpretation of a wall, as walls within houses are formed with two pieces of drywall and framing between them) defining an inner surface (inner surface is 44 in Fig. 12), an outer surface (labeled as 132 in Fig. 11) and a lumen extending from the proximal portion to an aperture in the distal portion (Fig. 12 discloses the lumen extending through to the aperture in the distal end); a steering wire (110a) having a distal portion; an anchoring member located within the distal portion of the elongate body wall between the inner surface and the outer surface and secured to the steering wire (the examiner is interpreting 134a as the anchoring member as this is what is directly secured to the steering wire and is secured to the distal end of the device (col. 11, lines 4-6)); a stiffening member (137) associated with the distal portion of the elongate body and defining a distal end (near 134a), the distal end of the stiffening member being directly secured to the anchoring member (Fig. 11); and a substantially tubular member (133) directly secured to the stiffening member and defining a continuous length in a direction parallel to the longitudinal axis and a wall thickness, the

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continuous length being substantially greater than the wall thickness (Fig. 11); wherein the steering wire is movable relative to the substantially tubular member (Fig. 12).

Kovalcheck, however, does not disclose that the elongate body wall is a substantially solid wall. Savage, however, discloses a similar device with similar support/steering structure (Figs. 7-18). Savage also discloses that these anchoring devices, stiffening members, anti-tear members and steering wires are positioned within the catheter wall, between the outer and inner surfaces of the wall (col. 6, lines 16-40). Therefore it would have been obvious to one of ordinary skill in the art to have modified Kovalcheck by making the body wall solid, as taught by Savage, as this wall surrounding the structures keeps the structures operational together and firmly in place and creates a stronger body which would be less prone to having elements rupturing the device when bent.

In reference to claim 73, Kovalcheck discloses a handle, operably connected to the elongate body and to the steering wire adapted to pull the steering wire relative to the elongate body (Figs. 2 and 6a-6c).

In reference to claim 74, Kovalcheck discloses that the steering wire extends to the proximal portion of the elongate body and is movable relative to the proximal portion of the elongate body (Figs. 2 and 6a-6c).

In reference to claim 92, Kovalcheck discloses that the anchoring member is directly secured to the steering wire (Fig. 11).

In reference to claim 99, Kovalcheck discloses that the substantially tubular member is located within the distal portion of the elongate body wall between the inner surface and the outer surface (Figs. 11 and 12).

.In reference to claims 102 and 103, Kovalcheck in view of Savage discloses the device substantially as claimed including a portion of the substantially solid wall being formed from a single wall material and the material extending from the inner surface to the outer surface (Fig. 2b for example discloses that the distal end just to the right of number 12 is a single solid wall material extending from the inner to the outer surface).

Claims 70, 93, 94 and 100 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kovalcheck (US Patent No. 5,472,017) in view of Savage et al. (US Patent No. 5,507,725). Kovalcheck discloses an apparatus (Figs. 2 and 9-12) substantially as claimed comprising: an elongate body defining a proximal portion and a distal portion (Fig. 2) and including a wall (Figs. 9-12, the wall is portion 26 as seen in Fig. 12, please note that the reference refers to 26 as a tubular member, and that the inner and outer surfaces are formed by 132 and 44. The examiner believes this is a reasonable interpretation of a wall, as walls within houses are formed with two pieces of drywall and framing between them, and Applicant has not claimed that the wall must be a solid wall with only two surfaces) defining an inner surface (inner surface is 44 in Fig. 12), an outer surface (labeled as 132 in Fig. 11) and a lumen extending from the proximal portion to an aperture in the distal portion (Fig. 12 discloses the lumen extending through to the aperture in the distal end); a steering wire (110a) having a distal portion; an anchoring member located within the distal portion of the elongate body wall between the inner surface and the outer surface and secured to the steering

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wire (the examiner is interpreting 134a as the anchoring member as this is what is directly secured to the steering wire and is secured to the distal end of the device (col. 11, lines 4-6)); a stiffening member (137) associated with the distal portion of the elongate body and defining a distal end (near 134a), the distal end of the stiffening member being directly secured to the anchoring member (Fig. 11); and a substantially tubular member (133) including a slot (the slot could be interpreted as the area between 133 and the next winding) directly secured to the stiffening member and defining a continuous length in a direction parallel to the longitudinal axis and a wall thickness, the continuous length being substantially greater than the wall thickness (Fig. 11); wherein the steering wire is movable relative to the substantially tubular member (Fig. 12).

Kovalcheck, however, does not disclose that the elongate body wall is a substantially solid wall. Savage, however, discloses a similar device with similar support/steering structure (Figs. 7-18). Savage also discloses that these anchoring devices, stiffening members, anti-tear members and steering wires are positioned within the catheter wall, between the outer and inner surfaces of the wall (col. 6, lines 16-40). Therefore it would have been obvious to one of ordinary skill in the art to have modified Kovalcheck by making the body wall solid, as taught by Savage, as this wall surrounding the structures keeps the structures operational together and firmly in place and creates a stronger body which would be less prone to having elements rupturing the device when bent.

In reference to claim 93, Kovalcheck discloses that the anchoring member is directly secured to the steering wire (Fig. 11).

In reference to claim 94, Kovalcheck discloses that the substantially tubular member is directly secured to the stiffening member (Figs. 11 and 12).

In reference to claim 100, Kovalcheck discloses that the substantially tubular member is located within the distal portion of the elongate body wall between the inner surface and the outer surface (Figs. 11 and 12).

Claims 45 and 79 are rejected under 35 U.S.C. 103(a) as being unpatentable over Umeda (US Patent No. 5,255,668) in view of Lundquist et al. (US Patent No. 5,848,986). Umeda discloses the device substantially as claimed including an apparatus (figs. 1-5) comprising: an elongate body (9) defining a proximal portion (near 50) and a distal portion (near 40) and including a wall defining an inner surface, an outer surface and a lumen extending from the proximal portion to an aperture in the distal portion (35); a steering wire (8a/8b) having a distal portion (near 40); an anchoring member (40 is connected to the tip and connected to 8a/8b as well as 10 via 20) of the elongate body, configured such that it does not obstruct the aperture in the distal portion of the elongate body (Fig. 5 discloses that 40 is a tube so that it does not obstruct 35), and directly secured to the steering wire (col. 6, line 68 through col. 7, line 3); means, directly connected to the anchoring member for preventing compression of the elongate body distal portion during bending of the elongate body distal portion (10); and a tubular member that is a partial circle in cross-section (50, because of slots 51a and 51b, this

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cross section is a partial circle) and has a slot (the interior passage of 50 that extends along the axis is being interpreted as the slot) in which a portion of the steering wire is located (Fig. 2 discloses that both steering wires are located with the slot of 50) positioned relative to the means for preventing compression so as to prevent the means for preventing compression from tearing through the elongate body when the means for preventing compression bends (this can be considered the anti-tear device equivalent to the applicant's anti-tear device, and furthermore, provides the same function of the anti-tear device, to spread out the force and stress placed on the steering wire). Umeda, however, does not disclose that the tubular member's slot includes first and second longitudinally extending edges that together define the slot in which the steering wire is located. Lundquist, however, discloses an embodiment in which the tubular member is a partial circle in cross-section and further includes first and second longitudinally extending edges that together define a slot, which extends completely through the tubular member at the first and second edges (Fig. 21 discloses that there is a slot in which the steering wire resides and the slot extends all the way through the tubular member as disclosed in a better depiction in Fig. 5 in which the slot and steering wire are exposed to the external surface/environment). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Umeda's device such that the tubular member included a longitudinally extending slot, as taught by Lunquist, such that the steering wire can slide freely with respect to the tubular member, and also to provide the device with a more compact shape and allow the device to be built with a smaller diameter.

In reference to claim 79, Umeda discloses that the elongate body defines a longitudinal axis (Figs. 1 and 2); the steering wire and the means for preventing compression are radially offset from the longitudinal axis (Fig. 2); and the steering wire and the means for preventing compression are substantially diametrically opposed from one another (Fig. 2).

Claims 52-54 and 86 are rejected under 35 U.S.C. 103(a) as being unpatentable over Umeda (US Patent No. 5,255,668) in view of Lundquist et al. (US Patent No. 5,848,986). Umeda discloses the device substantially as claimed including an apparatus (figs. 1-5) comprising: an elongate body (9) defining a proximal portion (near 50) and a distal portion (near 40) and including a wall defining an inner surface, an outer surface and a lumen extending from the proximal portion to an aperture in the distal portion (35); a steering wire (8a/8b) having a distal portion (near 40) operably connected to the distal portion of the elongate body (connected to 40 which is connected to the elongate body; Figs. 2 and 4); a stiffening member (10) associated with the distal portion of the elongate body (Fig. 2); and a substantially c-shaped anti-tear device (50, because of slots 51a and 51b, this cross section is a partial circle/c-shaped) with a slot (the slot is being interpreted as the opening within 50/the interior passage of 50 that extends along the axis is being interpreted as the slot) associated with the stiffening member (this can be considered the anti-tear device equivalent to the applicant's anti-tear device, and furthermore, provides the same function of the anti-tear device, to

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spread out the force and stress placed on the steering wire); wherein a portion of the steering wire is positioned within the slot (Fig. 2 discloses that both steering wires are located with the slot of 50). Umeda, however, does not disclose that the tubular member's slot includes first and second longitudinally extending edges that together define the slot in which the steering wire is located. Lundquist, however, discloses an embodiment in which the tubular member is a partial circle in cross-section and further includes first and second longitudinally extending edges that together define a slot, which extends completely through the tubular member at the first and second edges (Fig. 21 discloses that there is a slot in which the steering wire resides and the slot extends all the way through the tubular member as disclosed in a better depiction in Fig. 5 in which the slot and steering wire are exposed to the external surface/environment). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Umeda's device such that the tubular member included a longitudinally extending slot, as taught by Lunquist, such that the steering wire can slide freely with respect to the tubular member, and also to provide the device with a more compact shape and allow the device to be built with a smaller diameter.

In reference to claim 53, Umeda discloses that the elongate body defines a longitudinal axis and the stiffening member extends less than entirely around the longitudinal axis (Fig. 2).

In reference to claim 54, Umeda discloses that the anti-tear device extends further around the longitudinal axis than the stiffening member (Fig. 2).

In reference to claim 86, Umeda discloses that the elongate body defines a longitudinal axis (Fig. 2); the steering wire and the stiffening member are radially offset from the longitudinal axis (Fig. 2); and the steering wire and the stiffening member are substantially diametrically opposed from one another (Fig. 2).

Claims 71, 95, 96 and 101 are rejected under 35 U.S.C. 103(a) as being unpatentable over Matsuura et al. (US Patent No. 6,450,948) in view of Savage et al. (US Patent No. 5,507,725). Matsuura discloses the device substantially as claimed including an apparatus (Figs. 1-13 for example) comprising: an elongate body (40) defining a proximal portion (near 22) and a distal portion (near 28) and including a wall defining an inner surface, an outer surface and a lumen extending from the proximal portion to an aperture in the distal portion (Fig. 1 discloses the aperture as the opening in 40 which allows 28 to extend from and Fig. 4 discloses that the lumen is 34, also seen in Fig. 1); a steering wire (56 in the embodiment in Figs. 11 and 12 it is labeled as 356) having a distal portion; an anchoring member located in the distal portion of the elongate body and secured to the steering wire (Figs. 2-6 and 11, 50b/350b); a stiffening member (54a, 54b/354a, 354b) associated with the distal portion of the elongated body and defining a distal end (distal end is within 50b/350b), the distal end of the stiffening member being directly secured to the anchoring member (Figs. 2-6 and 11); and a substantially tubular member (50a/350a), which extends less than

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completely around the longitudinal axis (because of slot which 56 resides in, it can be said that 50a/350a extends less than completely around the longitudinal axis), secured to the stiffening member (Fig. 5) and defining a continuous length in a direction parallel to the longitudinal axis (50a/350a) and a wall thickness, the continuous length being substantially greater than the wall thickness (50a/350a is longer than the wall thickness). Matsuura, however, does not disclose that the anchoring member is located within the body wall between the inner surface and the outer surface. Savage, however, discloses a similar device with similar support/steering structure (Figs. 7-18). Savage also discloses that these anchoring devices, stiffening members, anti-tear members and steering wires are positioned within the catheter wall, between the outer and inner surfaces of the wall (col. 6, lines 16-40). Therefore it would have been obvious to one of ordinary skill in the art to have modified Matsuura by placing the entirety of the steering/anti-tear/stiffening structures within the wall of the catheter, as taught by Savage, as this wall surrounding the structures keeps the structures operational together and firmly in place and is a stronger body than fusing two different materials end to end as Matsuura does in Figs. 2, 4 and 5, for example, as these bonds would be subject to stresses when bending along their bond joint, whereas having a wall that surrounds this joint would provide a stronger device.

In reference to claim 95, Matsuura discloses that the anchoring member is directly secured to the steering wire (Fig. 4).

In reference to claim 96, Matsuura discloses the substantially tubular member is directly secured to the stiffening member (Fig. 5).

In reference to claim 101, Matsuura discloses the device substantially as claimed except for the tubular member being located within the body wall between the inner and outer surface. Savage, however, discloses a similar device with similar support/steering structure (Figs. 7-18). Savage also discloses that these anchoring devices, stiffening members, anti-tear members and steering wires are positioned within the catheter wall, between the outer and inner surfaces of the wall (col. 6, lines 16-40). Therefore it would have been obvious to one of ordinary skill in the art to have modified Matsuura by placing the entirety of the steering/anti-tear/stiffening structures within the wall of the catheter, as taught by Savage, as this wall surrounding the structures keeps the structures operational together and firmly in place and is a stronger body than fusing two different materials end to end as Matsuura does in Figs. 2, 4 and 5, for example, as these bonds would be subject to stresses when bending along their bond joint, whereas having a wall that surrounds this joint would provide a stronger device.

Claims 75-78 and 83-85 are rejected under 35 U.S.C. 103(a) as being unpatentable over Umeda (US Patent No. 5,255,668) in view of Matsuura et al. (US Patent No. 6,450,948) and further in view of Savage et al. (US Patent No. 5,507,725). Umeda in view of Matsuura discloses the device substantially as claimed except for the steering wire, stiffening member and anti-tear device being located in the body wall. Savage, however, discloses a similar device with similar support/steering structure (Figs. 7-18). Savage also discloses that these anchoring devices, stiffening members,

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anti-tear members and steering wires are positioned within the catheter wall, between the outer and inner surfaces of the wall (col. 6, lines 16-40). Therefore it would have been obvious to one of ordinary skill in the art to have modified Umeda in view of Matsuura by placing the entirety of the steering/anti-tear/stiffening structures within the wall of the catheter, as taught by Savage, as this wall surrounding the structures keeps the structures operational together and firmly in place and is a stronger body than fusing two different materials end to end as Umeda teaches, for example, as these bonds would be subject to stresses when bending along their bond joint, whereas having a wall that surrounds this joint would provide a stronger device, as well as for the purpose of allowing the size of the lumen to be larger and object-free in order to allow more versatility in use of the device.

Response to Arguments

Applicant's arguments filed 10/21/2009 have been fully considered but they are not persuasive. With respect to independent claim 71, it is still the examiner's position that it would have been obvious to place a wall, however, thin or thick, around the device of Matsuura as this would strengthen the device in that it would provide a sort of "lamine" or "cover" that surrounds the bonding sites of 50a and 50b to 52. Without such a cover/wall/lamine, the bonding sites may be more likely to pull apart at their seams, and a cover/wall would provide an extra layer externally and internally which would reinforce these bonding sites/seams.

In response to Kovalcheck not discloses the steering wire being diametrically opposite to the stiffening member, as included above, Kovalcheck does disclose such an embodiment.

In response to Umeda in view of Matsuura not discloses that the slot extends completely through the tubular member at the first and second edges, the examiner agrees that this is not shown by the secondary Matsuura reference and therefore has brought in the Lundquist reference instead as applied above.

In response to Kovalcheck not discloses a substantially solid wall, the examiner agrees and has brought in Savage as a secondary reference to show that it is obvious to one of ordinary skill in the art to place steering/strengthening materials within a solid wall.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LAURA C. SCHELL whose telephone number is (571)272-7881. The examiner can normally be reached on Monday-Friday 9am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Simons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Laura C Schell/
Examiner, Art Unit 3767

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/Kevin C. Sirmons/

Supervisory Patent Examiner, Art Unit 3767